

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
15 September 2005 (15.09.2005)

PCT

(10) International Publication Number  
**WO 2005/084377 A2**

- (51) International Patent Classification: Not classified (74) Agent: WHITE, John, P.; Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, NY 10036 (US).
- (21) International Application Number: PCT/US2005/007072 (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date: 3 March 2005 (03.03.2005)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/549,975 3 March 2004 (03.03.2004) US  
60/549,976 3 March 2004 (03.03.2004) US  
60/549,974 3 March 2004 (03.03.2004) US
- (71) Applicant (for all designated States except BB, US): TEVA PHARMACEUTICAL INDUSTRIES, LTD. [IL/IL]; 5 Basel Street, P.O. Box 3190, 49131 Petach-Tikva (IL).
- (71) Applicant (for BB only): TEVA PHARMACEUTICAL USA, INC. [US/US]; 1090 Horsham Road, North Wales, PA 19454 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): HAYARDENY, Liat [IL/IL]; Yehuda Hanasi 37, 69391 Tel-Aviv (IL). KLINGER, Ety [IL/IL]; 16, Agadati Street, Tel-Aviv 39930 (IL). BLAUGRUND, Eran [IL/IL]; 94 Remez Street, Rehovot (IL).
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— without international search report and to be republished upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2005/084377 A2

(54) Title: COMBINATION THERAPY WITH GLATIRAMER ACETATE AND RILUZOLE

(57) Abstract: The subject invention provides a method of providing neuroprotection to the central or peripheral nervous system of a subject in need of such neuroprotection comprising periodically administering to the subject an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzothiazole, wherein the amounts when taken together are effective to provide neuroprotection to the central or peripheral nervous system of the subject. The subject invention also provides a package comprising glatiramer acetate, 2-amino-6-trifluoromethoxybenzothiazole and instructions for use together to provide neuroprotection to the central or peripheral nervous system of a subject in need of such neuroprotection. Additionally, the subject invention provides a pharmaceutical composition comprising an amount of glatiramer acetate and an amount of 2-amino-6-trifluoromethoxybenzothiazole, wherein the amounts when taken together are effective to provide neuroprotection to the central or peripheral nervous system of the subject. The subject invention further provides a pharmaceutical combination comprising separate dosage forms of an amount of glatiramer acetate and an amount of 2-amino-6 trifluoromethoxybenzothiazole, which combination is useful to provide neuroprotection to the central or peripheral nervous system of the subject. In addition, the combination therapy may be used to treat a subject afflicted with multiple sclerosis or one afflicted with amyotrophic lateral sclerosis.